UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE DDAVP INDIRECT PURCHASER ANTITRUST LITIGATION	)	**05 cv 2237 (CS)**
	)	**HON. CATHY SEIBEL, U.S.D.J.**
THIS DOCUMENT RELATES TO: ALL ACTIONS	)	**ORAL ARGUMENT REQUESTED**

INDIRECT PURCHASER PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' JOINT MOTION TO DISMISS INDIRECT PURCHASER PLAINTIFFS' AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

BACKGROUND[1]

DDAVP and The '398 Patent

Desmopressin acetate is an antidiuretic, mainly used to control insipidus diabetes and bed wetting. Defendants Ferring and Aventis market their desmopressin acetate products under the brand name DDAVP. Am. Comp. ¶ 1. In the 1970s and 1980s, Defendants marketed several different versions of DDAVP (intranasal and injectable) pursuant to certain Ferring patents that claimed DDAVP. In anticipation of losing their patent exclusivity on DDAVP, Defendants devised a scheme to develop and market a DDAVP tablet protected by a new patent. Consistent with that plan, Ferring submitted a patent application ("the '398 application") with the Patent and Trademark Office ("PTO") in 1985 seeking to patent a tablet form of DDAVP.

During the '398 application process, the PTO examiners repeatedly concluded that Ferring's earlier patents "taught" or "suggested" that desmopressin acetate could be administered by mouth for gastrointestinal absorption, *i.e.*, tablet form, thus making a tablet unpatentable. Each time this issue came up, Ferring argued that the examiners simply misunderstood the import of the earlier patents. In response, the examiners requested "non-inventor" declarations supporting Ferring's interpretation of the earlier patents. Over the course of the '398 application, Ferring repeatedly filed several "non-inventor" declarations with the PTO in an effort to overcome the examiners' objections. Based on Ferring's "non-inventor" declarations, the PTO finally relented. On September 10, 1991, the '398 application led to the issuance of Patent No. 5,407,398 ("the '398 Patent"). Am. Comp. ¶¶ 50-69.

[1] Because of page limitations and the number of arguments that need to be addressed, Plaintiffs are unable to reproduce all of the Complaint's allegations relating to the federal regulatory scheme for approval of generic drugs. *See* Am. Comp.¶¶ 25-49.

As it turns out, the doctors who signed the "non-inventor declarations," which were submitted to the PTO by Ferring, were all paid consultants of Ferring. Am. Comp. ¶ 70. Not only had two of the doctors recently received research funding from Ferring (which was never disclosed to the PTO), but one of the other doctors had in fact been employed at Ferring as a "Research Director." And although the person shepherding the '398 application for Ferring noted on his CV (submitted to the PTO) that he had once been a "Research Director" at Ferring, the "independent" doctor's CV mysteriously omitted that fact. Am. Comp. ¶¶ 70-76.

Defendants' *Orange Book* Listing

In order to delay generic entry, Defendants listed the '398 patent in the FDA's *Orange Book.* Defendants knew that by listing the '398 patent in the *Orange Book* it would force generic companies to file a patent certification with the FDA relating to the '398 patent before obtaining FDA approval for its generic product. Defendants also knew that, under the Hatch-Waxman Act, this patent certification would allow them to immediately sue any generic manufacturer for patent infringement, which in turn, would trigger an automatic stay barring the generic manufacturer from launching its generic product for at least 30 months. In fact, as explained below, that is exactly what happened in this case. Am. Comp. ¶¶ 77-82.

Defendants' Sham Patent Infringement Litigation

Ferring began selling its DDAVP tablets in 1995. In 2002, Barr Laboratories, a generic manufacturer, submitted an ANDA (an application to permit the marketing of a generic drug) and a patent certification regarding the '398 Patent to the FDA. On December 13, 2002, Ferring and Aventis sued Barr based on the certification, asserting that Barr infringed the '398 Patent. Barr counterclaimed, arguing that the '398 Patent was unenforceable because Ferring engaged in

inequitable conduct before the PTO. Am. Comp. ¶¶ 83-86.[2]

On February 7, 2005, this Court (Judge Brient) granted summary judgment to Barr, holding that the '398 Patent was unenforceable due to Defendants' inequitable conduct before the PTO. *See Ferring B.V. v. Barr Lab.*, No. 02-9851, 2005 WL 437981 (S.D.N.Y. Feb. 7, 2005) ("*Ferring*"). Specifically, the Court held that "the entire record presents clear and convincing evidence of an intent to mislead the examiner" and that "the deceit was practiced over a long period of time by more than one person and appears to have been outcome determinative." The Court concluded that "the close and undisclosed long-standing associations between the declarants in this case and Ferring should have been disclosed in order to avoid the ***foreseeable inference of fraud*** that logically arises from the undisputed facts of this case." Am. Comp. ¶¶ 87-89.[3]

Ferring and Aventis appealed the ruling of inequitable conduct to the Federal Circuit. On February 15, 2006, the Federal Circuit affirmed this Court's decision, holding that "there is evidence in the summary judgment record supporting a conclusion that the past relationships [of Ferring's Declarants] were deliberately concealed." *See Ferring B.V. and Aventis Pharm. v. Barr Lab.*, 437 F.3d 1181 (Fed. Cir. 2006) ("*Ferring B.V.*"). The Federal Circuit added that Ferring's multiple omissions over a long period of time only heightened the seriousness of the conduct. *Id.* at 1194. But, as discussed below, Ferring and Aventis were not yet done gaming the system.

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[2] Defendants also filed a sham patent infringement action against Teva Pharmaceuticals to prevent them from entering the market with their generic DDAVP tablets. Am. Comp. ¶¶ 98-101.

[3] Defendants suggest that Judge Brient actually made a finding of "no fraud." Jt Mtn at 2. Defendants made a similar argument to the Second Circuit. It was unsuccessful. The Second Circuit held the argument to be a "logical non-sequitur." It further held that "the district judge could be correct in determining that inequitable conduct occurred and yet mistaken that such conduct did not amount to fraud. Moreover, the defendants' argument ignores the distinction between findings and pleadings. Even if the district judge was correct that the earlier record did not show fraud, the record in this case could be different following discovery." *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 692 (2d Cir. 2009).

Defendants' Citizen Petition

Knowing that the 30-month stay would be ending soon, Ferring filed a sham citizen petition with the FDA on February 2, 2004, to further delay generic entry. The citizen petition, among other things, requested extra testing to make sure generic DDAVP would be safe for children. On July 1, 2005, the FDA denied Ferring's citizen petition in its entirety, noting that Ferring failed to disclose a study by Aventis that was flatly inconsistent with the position advanced by Ferring.[4] Specifically, the FDA held that Ferring offered "no convincing evidence (*i.e.*, data or other information) that any of [the] proposed changes [were] needed. Accordingly, not having been presented with any basis for departing from our long-established and well-settled practice, we deny your petition in its entirety." Am. Comp. ¶¶ 102-116.

On the same day that the FDA denied Ferring's citizen petition, the FDA granted final approval to Barr to market generic DDAVP tablets. Thus, Defendants' scheme worked. The sham citizen petition actually delayed the entry of Barr's generic DDAVP. On July 15, 2005, Barr was finally able to launch its generic DDAVP product, but with a 180-day exclusivity period because of Defendants' act of filing the '398 Patent in the Orange Book. This caused even more damages to the Class. After Barr's exclusivity period ended, Teva came to market. Am. Comp. ¶¶ 117-19.

Purchasers of DDAVP File This Lawsuit

Direct and Indirect Purchasers Plaintiffs filed separate lawsuits in 2005 in this Court that were eventually coordinated. On November 2, 2006, the Court dismissed the complaints, holding that the Plaintiffs lacked antitrust standing and failed to state a claim upon which relief could be

[4] Federal regulations require a petitioner to identify and include all data and information known to the petitioner in the petition which may be unfavorable to the petition. *See* 21 C.F.R. § 10.30.

granted. Both Direct and Indirect Purchaser Plaintiffs appealed. Because the issues on appeal were essentially identical, the Indirect Purchaser Plaintiffs and Defendants agreed to stay the briefing on their appeal until the Directs' appeal was resolved. On October 16, 2009, the Second Circuit vacated the district court's dismissal of the Directs' case, finding that they did in fact have antitrust standing and had properly alleged their antitrust claims. *See In re DDAVP Direct Purchaser Antitrust Litig*., 585 F.3d 677 (2d Cir. 2009) ("*DDAVP*").

Direct Purchaser Plaintiffs have now settled their case with Defendants for more than $20 million. Final approval of the Direct Purchaser Plaintiffs' settlement with Defendants is currently scheduled for November 2, 2011. Soon after the Second Circuit handed down its opinion reversing the dismissal of the case, the Indirect Purchaser Plaintiffs and Defendants jointly requested that the Second Circuit dismiss the Indirect Purchaser Plaintiffs' appeal so that the parties could ask this Court to vacate the Amended Judgment previously entered against the Indirect Purchaser Plaintiffs. After the case was remanded, this Court vacated the Amended Judgment on July 8, 2011. On September 16, 2011, the Defendants served their Joint Motion to Dismiss ("Jt Mtn") on the Indirect Purchaser Plaintiffs.

Below, we show why Defendants' Joint Motion to Dismiss should be denied.

ARGUMENT

I. Plaintiffs' State-Law Claims Are Not Preempted by Patent Law

A. *Walker Process* and Sham Litigation

In *Walker Process Equip. v. Food Machinery*, 86 S. Ct. 347 (1965), Food Machinery had filed a fraudulent declaration with the PTO to secure its patent. After Food Machinery sued Walker Process for patent infringement, Walker Process counterclaimed for damages under the antitrust

laws. The Seventh Circuit dismissed the antitrust claim because it believed the antitrust claim was nothing more than a patent claim seeking to set aside the patent. *Id.* at 349. The Supreme Court disagreed. While one of the elements of Walker Process's antitrust claim might be to prove that Food Machinery committed fraud before the PTO, the Supreme Court nevertheless held that "the gist" of Walker Process's claim was to recover damages under the antitrust laws caused by Food Machinery's prosecution of its patent infringement case. *Id.* at 350. Proving fraud on the PTO, the Supreme Court added, was needed only to "strip Food Machinery of its exemption from the antitrust laws." *Id.*

The Court also found that permitting antitrust claims to go forward in such circumstances obviously advanced the public's "paramount interest in seeing that patent monopolies spring from backgrounds free from fraud . . . ." *Id.* As Justice Harlan recognized in his concurrence, permitting an antitrust claim to go forward based on the enforcement of a patent, but only if it can also be proven that the patent was obtained by fraud on the PTO, achieves a "suitable accommodation" between the differing policies of the patent and antitrust laws:

> To hold, as we do, that private suits may be instituted under section 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, ***cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure***. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play.

Id. at 351 (emphasis added). Similarly, in *Professional Real Estate Investors v. Columbia Pictures Indust.*, 113 S. Ct. 1920 (1993) ("*PRE*"), the Supreme Court held that, irrespective of conduct before the PTO, a party may also be held liable under the antitrust laws if that party files a patent infringement case that is nothing but a sham and causes antitrust damages. In *Nobelpharma AB v.*

Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998), the Federal Circuit summarized the holdings of *Walker Process* and *PRE*:

> A patentee who brings an infringement suit may be subject to antitrust liability for the anticompetitive effects of that suit if the alleged infringer (the antitrust plaintiff) proves (1) that the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process* or (2) that the infringement suit was a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.

Nobelpharma, 141 F.3d at 1068 (citations omitted).

Plaintiffs allege, as in *Walker Process*, that Defendants filed fraudulent declarations with the PTO in order to secure the '398 Patent and then filed sham patent infringement actions against Barr and Teva based on its fraudulent patent. Count II of Plaintiffs' Complaint asserts that this conduct, coupled with allegations outlining a monopolization claim (possession of monopoly power, relevant market, antitrust injury, etc.), states a claim under the antitrust and consumer protection statutes of 28 states. Defendants' immunity from Plaintiffs' antitrust claims will be "stripped from them" either by Plaintiffs proving that the '398 Patent was procured by fraud or by proving that the patent infringement actions were shams.

* * *

Neither the Supreme Court nor the Federal Circuit (nor any appellate court for that matter) has ever preempted a *Walker Process* antitrust claim.

B. Conflict Preemption

1. Presumption Against Preemption

One of the two "cornerstones" of the Supreme Court's preemption jurisprudence is the

presumption against preemption. *Wyeth v. Levine*, 129 S. Ct. 1187, 1194-95 (2009).[5] As the Court noted in *California v. ARC America*, 109 S. Ct. 1661, 1665 (1989), a party asserting the defense of preemption must "overcome the presumption against finding preemption of state law in areas traditionally regulated by the states." *See Medtronic v. Lohr*, 116 S. Ct. 2240, 2250 (1996) ("we start with the assumption that the historic police powers of the States were not to be superceded" by federal law "unless that was the clear and manifest purpose of Congress"). Focusing on antitrust conduct in particular, the Court went on to hold that "[g]iven the long history of state common-law and statutory remedies against monopolies and unfair business practices, it is plain that this is an area traditionally regulated by the States." *Id.* at 1665; *cf. Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 109 S. Ct. 971, 985 (1989) (law of unfair competition has coexisted harmoniously with federal patent law for almost 200 years); *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1334 (Fed. Cir. 1998) (the presumption against preemption has "greater force" in cases alleging state unfair competition claims because of the States' long history of providing remedies for monopoly and unfair business practices).

Thus, in the present case, which involves claims based on unfair competition and business practices, this Court should start with a presumption against finding preemption.

2. Purposes and Objectives

The modern test for conflict preemption can trace its origins back to *Hines v. Davidowitz*, 61 S. Ct. 399, 404 (1941). In *Hines*, the Supreme Court held that: "Our primary function is to determine whether, under the circumstances of this particular case, [the state law] ***stands as an***

[5] The other guiding principle is that "the purpose of Congress is the ultimate touchstone in every preemption case." *Wyeth*, 129 S. Ct. at 1194.

obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Since *Hines*, the "purposes and objectives" test has been repeatedly reaffirmed by both the Supreme Court and Federal Circuit.[6] Just this year, the Supreme Court confronted a conflict preemption issue and cited the purposes and objectives test: "Under ordinary conflict preemption principles a state law that stands as an obstacle to the accomplishment and execution of the full purposes and objectives of a federal law is preempted." *Williamson v. Mazda Motor of America, Inc.*, 131 S. Ct. 1131 (2011) (citing *Hines*) (holding that a state-law claim would not be preempted because the claim did not stand as an obstacle to the purposes and objectives of the federal Department of Transportation regulations).

Because Defendants argue that Plaintiffs' *Walker Process* and sham litigation claims should be preempted because they conflict with federal patent law, we turn next to the purposes and objectives of the patent laws, and whether Plaintiffs' *Walker Process* and sham litigation claims would undermine, frustrate or otherwise stand as an obstacle to those purposes and objectives.[7]

3. Plaintiffs' Claims Do Not Stand As An Obstacle to The Patent Laws' Three Purposes and Objectives

In *Aronson v. Quick Point Pencil Company*, 99 S. Ct. 1096, 1099 (1979), the Supreme Court identified three purposes and objectives of the patent laws: (1) patent law seeks to foster and reward

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[6] *See, e.g., Sears, Roebuck & Co. v. Stiffel*, 84 S. Ct. 784, 788-89 (1964) (preemption because granting patent-like protections under state law to an invention that is unpatentable under the federal patent law runs counter to Congressional policy of granting patents only to true inventions); *Bonito Boats*, 109 S. Ct. at 986 (preemption because offering patent-like protection for an invention unprotected under patent laws would conflict with the "strong federal policy favoring free competition in ideas which do not merit patent protection."); *Wyeth*, 129 S. Ct. at 1204 (no preemption because failure-to-warn claims do not obstruct the federal policies underlying the FDCA); *Hunter Douglas*, 153 F.3d at 1335 (remanding case so that district court could consider whether the state law actions frustrate the purposes and objectives of federal patent law); *Ultra-Precision Mfr. v. Ford Motor Co.*, 411 F.3d 1369, 1377 (Fed. Cir. 2005) (addressing conflict preemption under *Hines's* purposes and objectives test).

[7] This analysis would apply equally to Defendants' unlawful listing of its '398 Patent in the *Orange Book*.

invention; (2) patent law promotes disclosure of inventions in order to stimulate further innovation and to permit the public to practice the invention once the patent expires; and (3) patent law seeks to assure that ideas in the public domain remain there for the free use of the public. *See also Hunter Douglas*, 153 F.3d at 1333 (same); *Dow Chemical Co. v. Exxon Corp*., 139 F.3d 1470, 1474-75 (Fed. Cir. 1998) (same).

Thus, contrary to Defendants' position that preemption occurs when a state-law claim merely "encroaches upon federal patent law" (Jt Mtn at 6),[8] the relevant question to be asked in this case is whether Plaintiffs' state-law claims based on *Walker Process* and *PRE* stand as an *obstacle* to these three objectives. The question is not even close. Starting with *Walker Process* itself, the Supreme Court was required to balance the policies between the antitrust laws and the patent laws. The Court ultimately held that the patent laws must give way to the antitrust laws if the plaintiff can prove fraud on the PTO. The Court permitted antitrust claims to go forward in these circumstance because such a claim obviously does not implicate any Congressional policy underlying the patent laws. Again, as Justice Harlan noted in his concurrence in *Walker Process*, antitrust lawsuits based on "a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure." *Walker Process*, 86 S. Ct. at 351; *see also Dow*, 139 F.3d at 1475 ("It is difficult to fathom how such a state law cause of action [state-law tortious interference claim based on a bogus patent] could have any discernible effect on the incentive to invent, the full disclosure of ideas, or the principle that ideas in the public domain remain in the public domain.").

[8] The "Supreme Court has repeatedly confirmed that federal patent law issues housed in a state law cause of action are capable of being adjudicated, even if there is no accompanying federal claim." *Hunter Douglas*, 153 F.3d at 1334.

Similarly, in *Zenith Electronics Corp. v. Exzec*, 182 F.3d 1340, 1352 (Fed Cir. 1999) ("*Exzec*"), the Federal Circuit held that *Walker Process* and *PRE*[9] were decisions aimed at achieving a suitable balance between the differing policies of the antitrust and patent laws. "The accommodation has been achieved by erecting certain barriers to antitrust suits against a patentee attempting to enforce its patent." *Id.* at 1352. The Federal Circuit cites *Nobelpharma's* summary of *Walker Process* and *PRE* as the accommodation. In other words, so long as the patentee either defrauded the PTO or asserted sham patent infringement suits, the patentee can be sued for antitrust violations. Underlying this accommodation, the court notes, is the fact that recognizing any claim based on PTO fraud or bad faith conduct involving a patent has "no discernable effect on the three objectives of the patent laws" identified by the Supreme Court. *Id.* at 1354.

In this case, Plaintiffs have alleged the standard elements of state-law antitrust and consumer protection claims. Consistent with *Walker Process*, *PRE* and *NobelPharma*, Plaintiffs have also alleged that the '398 Patent was procured by fraud on the PTO and that the Defendants used the '398 Patent to then initiate sham patent infringement lawsuits. Because, as discussed above, state-law claims based on a fraudulent patent or sham litigation in no discernable way implicate the policies underlying the patent laws, let alone stand as an obstacle to the accomplishment and execution of those policies, Plaintiffs' state-law claims are not preempted by the patent laws. *See DDAVP*, 585 F.3d at 690 ("*Walker Process* itself, of course, reflects a willingness to let antitrust liability impact the patent system.").

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[9] The court actually cites *Handsgard, Inc. v. Ethicon, Inc.*, 601 F.2d 986 (9th Cir. 1979), which is a precursor to the Supreme Court's decision in *PRE*. The Ninth Circuit held in *Handsgard* that "infringement actions initiated and conducted in bad faith contribute nothing to the furtherance of the policies of either the patent law or the antitrust law." *Id.* at 993.

4. Preemption Will Not Prevent *Walker Process* Claims From Being Litigated

Conflict preemption essentially asks whether a state-law claim should never see the light of day because, if allowed to proceed, it would frustrate the purposes and objectives of a federal law. For instance, when the Supreme Court preempts a state law because it grants a patent for unpatentable inventions, ***that ruling prevents anyone from using that particular state law again to pursue such an action***. *See, e.g., Sears and Bonito Boats, supra. Walker Process* claims are a different animal. *Walker Process* fraud may not only be pursued through state law, but also through federal law. In other words, unlike the normal case where preemption of a state-law claim prevents that claim from ever being litigated, preemption of a state-law *Walker Process* claim will never prevent others from raising *Walker Process* claims based on the identical conduct.

In fact, in this case, no less than three groups of plaintiffs have brought *Walker Process* claims (or could have), none of which are in danger of being preempted. For example, although Barr and Teva chose not to file *Walker Process* claims against Defendants, Defendants cannot dispute that they had the right to do so. Moreover, before they settled, the Direct Purchaser Plaintiffs alleged *Walker Process* claims. *See DDAVP*, 585 F.3d at 695. Finally, and perhaps most telling, the Indirect Purchaser Plaintiffs themselves have brought a *Walker Process* claim in Count I under federal law that is not subject to preemption.

If it is undisputed that at least three other plaintiff groups are permitted to raise *Walker Process* claims that are not subject to preemption, it is difficult to fathom how one more *Walker Process* claim brought via a state-law statute could in any way undermine the patent laws' three policy objectives. In fact, it defies logic to suggest otherwise because once the Supreme Court

balanced the policies between the antitrust laws and patent laws to permit a *Walker Process* claim to go forward under federal law, the Supreme Court set the standard for ***any and all*** *Walker Process* claims to go forward. Because the objectives of the patent laws are not concerned with whom asserts a *Walker Process* claim, nor the source of the cause of action that will remedy the *Walker Process* fraud, state-law claims based on *Walker Process* fraud by Indirect Purchaser Plaintiffs in this case simply do not frustrate any of the patent laws' policies or objectives.

A similar situation was confronted by the Federal Circuit in *Zenith Electronics Corp. v. Exzec*, 182 F.3d 1340 (Fed Cir. 1999). In *Exzec*, the Federal Circuit addressed two issues: (1) whether a federal unfair competition claim under the Lanham Act was preempted by patent law; and (2) whether a state antitrust claim was preempted by patent law. The Federal Circuit noted that preemption analysis would not apply to the first issue since no state claim was at issue. Instead, the court's task was to interpret both statutes in a way that "preserves the purposes of both and fosters harmony between them." *Id.* at 1347. With this principle in mind, the Federal Circuit ruled that the Lanham Act claim could proceed so long as the plaintiff also proved bad faith. *Id.* at 1354-55 (recognizing that bad faith requirement for Lanham Act claim is analogous to its decision in *Hunter Douglas* requiring bad faith to prevent preemption of state-law claim).

Turning to the second issue – whether the state law claim, which was based on the same conduct supporting the Lanham Act claim, should be preempted – the Federal Circuit held, not surprisingly, that so long as Exzec again proved bad faith (along with the other elements of its tortious interference claim), the claim would not be preempted because such a conclusion would be "consistent with the analysis previously set forth" with regard to whether the federal Lanham Act claim should proceed. *Id.* at 1355. In other words, it made no sense to preempt a state-law claim

based on anticompetitive conduct after having concluded that a federal claim premised on the identical conduct should go forward.

Likewise, once the Supreme Court in *Walker Process* balanced the policies between the antitrust and patent laws, concluding that an antitrust claim could be brought based on fraudulent conduct before the PTO, ***it set the standard for all Walker Process claims***. Thus, whether or not the *Walker Process* claim is traveling under federal or state law is of no moment because, logically, neither stands as an obstacle to the accomplishment of the patent laws' purposes and objectives.

5. Cases Cited by Defendants Do Not Support Preemption

In regards to *Walker Process* claims, the claims at issue in this case, Defendants do not cite a single Supreme Court case that holds that patent law preempts a state-law claim based on *Walker Process* fraud. Neither do Defendants cite a Federal Circuit case that preempts a state-law claim based on *Walker Process* fraud. Instead, Defendants rely on the reasoning of *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F.Supp.2d 514 (E.D.N.Y. 2005) ("*Cipro*"), *aff'd on other grounds*, 544 F.3d 1323 (Fed. Cir. 2008) (affirmed because of lack of fraud).[10] *Cipro*, however, does not even mention the patent laws' three purposes and objectives, let alone discuss whether the *Walker Process* claim stood as an obstacle to the accomplishment of those objectives.

How then did the court in *Cipro* determine that the plaintiffs' *Walker Process* claim was

[10] Defendants also refer the Court to *In re K-Dur Antitrust Litig.*, No. 01-1652, 2007 WL 5297755 (D.N.J. Mar. 1, 2007) and *Daiichi Sankyo, Inc. v. Apotex*, Inc., No. 030937, 2009 WL 1437815 (D.N.J. May 19, 2009). But these two New Jersey cases rely on *Cipro* for their "analysis." Moreover, in *K-Dur*, Special Master Orlofsky holds, which no one would dispute, that all *Walker Process* claims "suffer" from the same "defect," that is, "they fundamentally rely upon evidence of fraud or inequitable conduct before the PTO . . . ." *Id.* at *24. Having recognized the obvious, the Special Master then makes a leap of logic to hold that a *Walker Process* claim somehow constitutes "an impermissible attempt to offer patent-like protection." *Id.* In *Daiichi*, the court actually dismissed Apotex's *Walker Process* fraud claim because Apotex was barred by the law of the case doctrine from revisiting the court's ruling that no inequitable conduct occurred before the PTO. The claims preempted in *Daiichi* were a tortious interference and unjust enrichment claim. These claims obviously could not be sustained as *Walker Process* fraud claims once it had been decided that Apotex was barred from proving fraud, irrespective of any ill-advised preemption analysis based on *Cipro*.

preempted by the patent laws? It determined the following: (1) Under *Christianson v. Colt Indus.*, 108 S. Ct. 2166 (1988), which deals with jurisdiction of patent law claims, plaintiffs' *Walker Process* claim obviously rests "entirely on patent law"; and (2) *Walker Process* claims do not allege any conduct other than conduct before the PTO. *Cipro*, 363 F.Supp.2d at 543-44. Not only did the *Cipro* court fail to use the correct test for preemption, but the test it did use does not make much sense. Even the Federal Circuit, the court which affirmed the district court (notably, on *other* grounds), was not sure how the district court reached its result. It observed that it was not entirely clear that the district court, in reaching its preemption ruling, read and considered everything the Federal Circuit held in *Hunter Douglas* and *Nobelpharma*. *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 544 F.3d 1323, 1340-41 (Fed. Cir 2008) ("*Cipro II*").

The district court in *Cipro* first concluded that the claims were preempted under *Christianson*. Yet *Christianson* simply sets out the test on whether a claim "arises under" patent law to determine whether a court has proper jurisdiction. *See DDAVP*, 585 F.3d at 684-85 (discussing *Christianson* in determining whether the Second Circuit had jurisdiction). The court first acknowledges that the two principles of jurisdiction and conflict preemption are distinct, but nevertheless holds, without any legal support, that the two are "closely related." *Cipro*, 363 F.Supp.2d at 543 n. 26. But the two tests are not closely related.[11] There is simply no excuse for using *Christianson* to hold that a *Walker Process* antitrust claim is a patent claim. The fact that a plaintiff is required to allege fraud on the PTO in a *Walker Process* claim is quite unremarkable, and

[11] The question whether a cause of action "arises under" patent law such as to invoke the exclusive jurisdiction of a federal court is separate from the question whether it is preempted by patent law. *See Animal Legal Defense Fund v. Quigg,* 900 F.2d 195, 197 (9th Cir. 1990) (preemption and jurisdiction are different legal issues); *Hunter Douglas*, 153 F.3d at 1329 (holding that just because antitrust claims "arise under" patent law for purposes of federal court jurisdiction does not mean that they are preempted by patent law); *Dow*, 139 F.3d at 1477 (same).

certainly does not lead to the conclusion that the Supreme Court (and every other court that does not rely on *Cipro*) got it wrong when they held that a *Walker Process* claim is an antitrust claim.[12] Even the Federal Circuit, who heard the appeal from the *Cipro* court's decision, held that a *Walker Process* claim is an antitrust claim. *See Cipro II*, 544 F.3d at 1329-30.[13] *See also Unitherm Food Sys. v. Swift-Eckrich*, 375 F.3d 1341, 1349 (Fed. Cir. 2004) (recognizing that a *Walker Process* claim is not a patent claim, but rather an "antitrust claim premised on the bringing of a patent infringement suit."); *Molecular Diag. v. Hoffman-La Roche*, 402 F.Supp.2d 276, 280-81 (D.D.C. 2005) (holding that a *Walker Process* claim "is not a fraud claim." Rather, "[v]iewed properly," it is an "antitrust claim.").

Having found that plaintiffs' *Walker Process* antitrust claim arises under patent law, and in fact rests entirely on patent law, it does not come as much of a surprise that the court also concluded that the *Walker Process* claim was like an abuse of process claim found to be preempted in *Abbott Labs. v. Brennan*, 952 F.2d 1346 (Fed. Cir. 1991). But *Brennan* is yet another case cited by Defendants that does not involve a *Walker Process* claim.[14] *Brennan's* holding can be summarized

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[12] In *Walker Process*, the Supreme Court held that a *Walker Process* claim is a claim "under the Clayton Act, not the patent laws." *Walker Process*, 86 S. Ct. at 350. The fraud-on-the-PTO element serves only "to strip" the patentee's immunity under the antitrust laws so that the antitrust claim can go forward. *Id.* *See also Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1341, 1346 (Fed. Cir. 2007) (*Walker Process* claim is an antitrust claim); *Nobelpharma,* 141 F.3d at 1071 ("*Walker Process* antitrust liability is based on the knowing assertion of a patent procured by fraud on the PTO"); *DDAVP*, 585 F.3d at 692 (analyzing whether plaintiffs have antitrust standing to assert *Walker Process* claim).

[13] Perhaps most puzzling is the *Cipro* court's observation that "there is simply no theory for proving a *Walker Process* antitrust violation in this case that would not require a showing of misconduct before the PTO." *Cipro*, 363 F.Supp.2d at 543. Of course, this statement is true for any *Walker Process* claim – fraud on the PTO must be proven to strip the patentee of its antitrust immunity to prosecution. Having recognized this tautology – all *Walker Process* claims require an allegation of fraud on the PTO – the court unfortunately jumps to the conclusion that the *Walker Process* claim in front of it must therefore be a claim that "arises out of patent law." But, of course, this conclusion is contrary to every Supreme Court and appellate court ruling that has involved *a Walker Process* claim.

[14] In fact, the Federal Circuit affirmed the dismissal of an alleged *Walker Process* claim in *Brennan* not because of preemption but because the plaintiff did not adequately allege market power. *Brennan*, 952 F.2d at 1355. We would also note that the Federal Circuit in *Brennan* neither sets out, nor addresses, the Supreme Court's test for preemption.

as follows: a plaintiff cannot bring a state-law claim as a remedy for inequitable conduct, as opposed to fraud, in front of the PTO. *See also Semiconductor Energy Lab. v. Samsung Elec. Co.*, 204 F.3d 1368 (Fed. Cir. 2000) (cited by defendants) (no *Walker Process* claim; mere inequitable conduct before PTO insufficient to state an independent state-law claim); *Sign-A-Way, Inc. v. Mechtronics Corp*., 232 F.3d 911 (Fed Cir. 2000) (cited by defendants) (same). In fact, the Federal Circuit in *Brennan* held that had the plaintiffs alleged that defendants' conduct before the PTO was a sham, their claim would not have been preempted. *Id.* at 1356. *Cipro* simply did not adhere to Supreme Court precedent when it decided that the *Walker Process* should be preempted. *Cipro*,[15] and the cases that rely on it, should therefore be discounted accordingly by this Court.

II. Plaintiffs' State-Law Claims Are Not Preempted by the FDCA

A. Plaintiffs Allege an Antitrust Claim Based on Defendants' Sham Citizen Petition

Because government petitioning is generally immune from antitrust liability under the First Amendment, a plaintiff may not raise a claim based on a citizen petition unless it is alleged to be a sham. As discussed above in connection with Plaintiffs' *Walker Process* claim, the Supreme Court has determined that the "sham exception" requires that the petition be both: (1) objectively baseless; and (2) subjectively baseless, *i.e.,* an attempt to interfere directly with the business relationships of a competitor through the use of governmental process. *See DDAVP*, 585 F.3d at 686 (quoting *PRE*).

In connection with their citizen petition claim, Plaintiffs have alleged, in addition to the standard elements of a monopolization claim, that Ferring filed the sham citizen petition with the

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In fact, the panel in that case does not even mention the word "preemption" until the last sentence in the opinion. *Id.* at 1357.

[15] *Cipro* was also handed down long before the Second Circuit clarified in this case that purchaser plaintiffs have standing to raise *Walker Process* claims with respect to an already "tarnished patent." *DDAVP*, 585 F.3d at 691. The patent challenged in *Cipro* was upheld at least three times. *See Cipro*, 363 F.Supp.2d at 519-20.

FDA with the sole intent to delay Barr's generic entry, thereby satisfying *PRE's* subjective component. *See Ferring*, 2005 WL 437981, at *17 (holding that the citizen petition might have been "nothing more than a hardball litigation tactic, motivated by a desire to keep out competition for as long as possible after the expiration of the patent and raise transactional costs for Barr.").

Plaintiffs have also alleged that the citizen petition was objectively baseless. The citizen petition, among other things, requested for extra testing to make sure generic DDAVP would be safe for children. On July 1, 2005, the FDA denied Ferring's citizen petition in its entirety, noting that Ferring failed to disclose a study by Aventis that was flatly inconsistent with the position advanced by Ferring. As the Second Circuit observed, the FDA "found that the citizen petition 'had no convincing evidence' and lacked '***any basis***' for its arguments." *DDAVP*, 585 F.3d at 694 (emphasis supplied). The Second Circuit held that these allegations, regarding both subjective and objective baselessness, plausibly show that the Ferring citizen petition was nothing but a sham. *Id.* at 694.

The Second Circuit also held that the allegations sufficient to satisfy *PRE's* sham exception to the First Amendment only deprive Ferring of its immunity from the antitrust laws. *Id.* at 686. In other words, proving that the citizen petition is a sham cannot alone prove liability. Proving all of the other elements that make up a Section 2 antitrust claim proves liability. Thus, the sham exception works like the fraud-on-the-PTO element in a *Walker Process* claim. Sham allegations strip Ferring of its First Amendment immunity in connection with the citizen petition claim. And the fraud-on-the-PTO allegations strip Defendants of their patent immunity with regard to the *Walker Process* claim. Properly understood, therefore, Plaintiffs' sham citizen petition claim is an antitrust claim just as a *Walker Process* claim is an antitrust claim. *Id.* at 685-95.

B. Plaintiffs' Sham Citizen Petition Claim Does Not Stand As An Obstacle to the FDCA's Purposes and Objectives

Defendants argue that Plaintiffs' antitrust claim based on the sham citizen petition should be preempted because allowing such a claim would conflict with the purposes and objectives of the Food, Drug, and Cosmetic Act ("FDCA"). Defendants rely on *Buckman Co. v. Plaintiffs' Legal Comm.*, 121 S. Ct. 1012 (2001), to support this argument. *Buckman*, however, did not involve an antitrust claim based on a sham citizen petition.

In *Buckman*, plaintiffs brought a claim against a consulting company that assisted a manufacturer of orthopedic bone screws with the filing of an FDA application. *Buckman*, 121 S. Ct. at 1015. Plaintiffs' claim was simply that "but for" the consulting company's alleged fraud during the application process, the FDA would not have approved the screws, and plaintiffs would not have been injured. That was the entirety of plaintiffs' claim. *Id.* The Supreme Court deemed such a claim to be nothing more than a "fraud-on-the-FDA" claim because the claim "exist[ed] solely by virtue of the FDCA disclosure requirements." *Id.* at 1020. *Buckman* did not involve an antitrust claim (or any traditional state tort claim for that matter). In fact, in *Buckman*, the Supreme Court distinguished two of its prior cases based on the particular causes of action at issue in those cases. For instance, the Court observed that in *Silkwood v. Kerr-McGee Corp*., 104 S. Ct. 615 (1984), it did not find preemption because the plaintiff's claim was based on "traditional state law tort principles of the duty of care" (*i.e*., negligence). Likewise, the Court characterized its finding of no preemption in *Medtronic* as being based on the fact that the case involved a "common-law negligence [claim] against the manufacturer of an allegedly defective pacemaker lead." *Buckman*, 121 S. Ct. at 1019.

Because the claim in *Buckman* was not a traditional state-law claim, but rather a fraud-on-the-FDA claim, the Court held that such a claim would interfere with the federal statutory scheme that allows the FDA to punish and deter fraud. *Id.* at 1017-18.[16] Claims that are nothing more than fraud-on-the-FDA claims interfere with the FDCA's objective to allow the FDA to police fraud on the agency, but claims that are based on traditional common-law torts do not interfere with that particular FDCA objective.

As established above, Plaintiffs' sham citizen petition claim is not a fraud-on-the-FDA claim. It is an antitrust claim – a traditional state-law claim – and Plaintiffs must prove all of the standard elements of a Section 2 monopolization claim to prevail on that count. Showing that Defendants engaged in fraudulent behavior by filing a sham citizen petition only rebuts Defendants' affirmative defense of First Amendment immunity. For these reasons, *Buckman* is inapplicable to the facts of this case.

In a footnote, Defendants also ask this Court to disregard the Second Circuit's opinion in *Desiano v. Warner-Lambert*, 467 F.3d 85 (2d Cir. 2007). Jt Mtn at 12 n. 4. Wishful thinking. *Desiano* strongly militates in favor of not finding preemption in this case. In *Desiano*, the Second Circuit addressed whether a state statute that granted immunity to drug makers for compliance with FDA requirements, but which had an exception if the drug maker committed fraud on the FDA, should cause traditional product liability claims to be preempted. *Id.* at 87-88. In deciding against preemption, the Second Circuit distinguished *Buckman* on three grounds. First, it applied the presumption against preemption. The state statute at issue could hardly "be characterized as a state's

[16] The Court noted that the presumption against preemption should not apply because "policing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Buckman*, 121 S. Ct. at 1017.

attempt to police fraud against the FDA." *Id.* at 94. Instead, the court found that the state legislature's intent in enacting the statute was to rein in state-based tort liability, a matter falling squarely within a State's traditional police power. *Id.*

Second, the court found that the plaintiffs were not asserting "fraud-on-the FDA" claims as the plaintiffs were in *Buckman*. Rather, their claims "are premised on traditional duties between a product manufacturer and consumers. None of them derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency." *Id.* at 94-95. In fact, the Second Circuit understood *Buckman* to hold that, for a claim to be deemed a "fraud-on-the-FDA" claim, "proof of fraud against the FDA [must be] *alone sufficient* to prove liability." *Id.* Thus, "*Buckman* cannot be read as precluding such preexisting common law liability based on other wrongs, even when such liability survives only because there was *also* evidence of fraud against the FDA." *Id.*

Third, the Second Circuit held that, unlike *Buckman*, proof of fraud on the FDA is not an element of a products liability claim. Rather, the fraud becomes relevant only if the drug maker asserts statutory immunity as an affirmative defense. *Id.* at 96 (the statute in question "does no more than create a defense that drug makers may invoke, if they so decide, and that it is not up to the plaintiff to prove fraud as an element of his or her claim."). Because fraud only becomes relevant as a legal parry to an affirmative defense, the Second Circuit could not read the FDCA as preempting such a claim:

> Finding preemption of traditional common law claims where fraud is not even a required element – but may be submitted to neutralize a drug maker's use of an affirmative defense available under state law – would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect.

Id. at 96.

Applying *Desiano* to the facts of this case leads to the inescapable conclusion that *Buckman* does not apply.[17] First, as was the case in *Desiano*, the presumption against preemption applies in this case because the citizen petition claim is an antitrust claim. And there is no evidence that when this cause of action was created (well before the FDCA was enacted) it was done with the sole purpose to police fraud against the FDA. Second, in order to prove the antitrust claim, proof of fraud against the FDA alone is *insufficient* to prove liability. An antitrust claim is a traditional state-law claim that *Buckman* would not preempt just because "such liability survives only because there was *also* evidence of fraud against the FDA." Finally, fraud on the FDA is not an element of an antitrust claim because, like *Desiano*, proof of fraud only arises as an issue if the Defendants assert immunity as an affirmative defense. Proving fraud on the FDA, in the words of the Second Circuit, is needed only to "neutralize" Defendants' immunity defense.

Thus, under both *Buckman* and *Desiano*, Plaintiffs' sham citizen petition should not be preempted.[18]

III. Plaintiffs May Seek Injunctive Relief Under Section 16 of the Clayton Act

Defendants correctly point out that injunctive relief is proper under Section 16 of the Clayton

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[17] *Desiano* also support Plaintiffs' argument, *supra*, that *Walker Process* claims should not be preempted. Fraud is not an element of an antitrust claim, a claim which is a traditional state-law cause of action. Moreover, proof of fraud on the PTO is needed only to strip the patentee of its patent immunity.

[18] As was the case for Plaintiffs' *Walker Process* claims, preempting Plaintiffs' citizen petition claim will not prevent these claims from being filed and tried. The Supreme Court has already balanced the policies behind the First Amendment's right to petition the government against the objectives of the antitrust laws, concluding that so long as the plaintiff can prove that the government petition is a sham, the claim may go forward. That is why Defendants' competitors and the Direct Purchaser Plaintiffs (before they settled) had the right to litigate the citizen petition claim. And that is why the Indirect Purchaser Plaintiffs (under Count I for equitable relief) will still be able to litigate the citizen petition claim even if this Court were to find preemption appropriate in this case.

Act when there is "threatened loss or damage." *See* Jt Mtn at 4-6 (citing cases holding that injunctions may only be granted where "there exists some cognizable danger of recurrent violation" or "to forestall future violations."). But then they argue that Count I, which seeks injunctive relief under Section 16, should be dismissed because the '398 Patent was declared unenforceable in 2005. While it is true that an injunction is no longer needed to prevent Defendants from filing more sham patent infringement cases against generic manufacturers of DDAVP, Count I is about more than just the fraudulent '398 Patent.

Count I also seeks injunctive relief from this Court "to assure that similar anticompetitive conduct does not occur in the future" whether related to DDAVP or any other drug that Plaintiffs may be forced to pay supracompetitive prices down the road. Am. Comp. ¶ 138. As the Supreme Court held in *Zenith Radio Corp. v. Hazeltine*, 89 S. Ct. 1562, 1580 (1969) ("*Zenith*"), to obtain an injunction, a plaintiff "need only demonstrate a significant threat of injury . . . from a contemporary violation likely to continue or recur."[19] *See also Commodities Futures Trading Comm. v. American Board of Trade, Inc.*, 803 F.2d 1242, 1250-51 (2d Cir. 1986) ("A district court may properly infer a likelihood of future violations from the defendant's past unlawful conduct.").

There is no question that, over the years, Defendants have shown a certain proclivity for unlawful conduct when it comes to maintaining their drug monopolies. For example, this is not

[19] In *Zenith*, the Supreme Court affirmed an injunction barring a defendant from conspiring with others to restrict Zenith from entering other foreign markets "given the findings that [the defendant] was conspiring with the Canadian [patent] pool" as well as its "propensity for arrangements of this sort" indicated by "its participation in similar [patent] pools operating in England and Australia." *Id.* at 1581. Zenith, the Court held, was entitled to injunctive relief against "*like conduct*" by the defendant "*in other world markets*." *Id.* at 1581-82 (emphasis supplied) ("Although a district court may not enjoin all future illegal conduct . . . it is not necessary that all of the untraveled roads to that end be left open and that only the worn one be closed.").

Ferring's first time to have been accused of manipulating the PTO by filing false declarations. In *The Salk Institute for Biological Studies v. Ferring Pharm., Inc.*, No. 10-2649 (S.D. Cal.), The Salk Institute alleged that Ferring hired a Salk Institute researcher, Dr. Rivier, with the intent to use the information he gained from over 25 years of research at The Salk Institute regarding GnRH antagonist peptides. But when Ferring ultimately filed two patent applications in the late 1990s related to a GnRH antagonist peptide called Degarelix (used to treat prostate cancer), Ferring omitted Dr. Rivier as an inventor. Years later, at the request of Dr. Rivier, Ferring finally added Dr. Rivier as an inventor. The Salk Institute alleged that the initial omission was intentional, and that Dr. Rivier was "coached, counseled, instructed, encouraged and/or directed" by Ferring not to disclose the fact of his inventorship until November 10, 2009, so that Ferring, rather than The Salk Institute, would be assigned the patent rights. *See* Req. Ex. 1 at 7-16.[20]

Just last year, Aventis also engaged in inequitable conduct before the PTO. In *Aventis Pharma. and Sanofi-Aventis U.S., LLC v. Hospira, Inc. and Apotex, Inc.*, Nos. 07-721& 08-496 (D. Del.), Chief Judge Sleet held that, in prosecuting a patent application for Taxotere, a cancer drug, Aventis deliberately withheld references from the PTO despite knowing that it had a duty to disclose them. *See* Req. Ex. 2 at 57-66 (noting that Aventis engaged in a "course of conduct" of "intentionally withholding highly material prior art from the patent office during the prosecution of the patents-in suit" and that the "evidence of deceptive intent is clear and compelling.").

Similarly, in January 2007, in *Teva Pharmaceuticals v. Aventis Pharmaceuticals Inc.*, No. 06-5463 (D.N.J.), Aventis was charged with repeatedly filing a false declaration with the PTO to

[20] Plaintiffs have filed a Request for Judicial Notice of various public pleadings cited herein that can be found on PACER. Citations to the Request's attachments shall be "Req Ex. __ at __."

overcome various objections of the patent examiner while prosecuting a patent application for the drug Allegra (facts that are virtually identical to the facts of this case). *See* Req. Ex. 3 at 8-14 (with the intent to deceive, Aventis withheld material facts from, and made false and misleading statements to, the PTO). Aventis's misconduct in prosecuting its Allegra patents is similar to what was alleged by yet another plaintiff in *Aventis Pharma S.A. v. Baxter Healthcare Corp.*, No. 06-00636 (D. Del.). That case involved Aventis's prosecution of a patent related to the drug Advate, which treats hemophilia. Baxter alleged that Aventis, with the intent to deceive the PTO, withheld at least three prior art references from the PTO, submitted misleading statements, and filed a false declaration. *See* Req. Ex. 4 at 9-28.

Another example of Aventis's unlawful conduct involved the blood thinner Lovenox. Aventis, similar to what it did with DDAVP (and consistent with what it did with Taxotere, Allegra, and Advate), submitted a false declaration to the PTO to secure a bogus patent and filed a sham patent infringement case based on that patent against Amphastar, a generic competitor. On February 8, 2007, after a bench trial, the judge in *Aventis Pharma S.A. v. Amphastar Pharm., Inc*., 475 F.Supp.2d 970, 994 (C.D. Cal. 2007), *aff'd,* 525 F.3d 1334 (Fed. Cir. 2008), held that Amphastar had proven by clear and convincing evidence that Aventis intended to deceive the PTO.[21]

As can be seen from the above, in addition to the bad acts alleged in this case, Defendants have been plenty busy in other cases. Specifically, they have filed false declarations with the PTO, withheld prior art references from the PTO, submitted false and misleading statements to the PTO,

[21] Although Amphastar could not ultimately prove antitrust injury during the prosecution of its antitrust counterclaim (Amphastar's ANDA was never approved by the FDA), the court held that Amphastar had pleaded a *Walker Process* claim against Aventis ("Amphastar adequately alleges that Aventis was aware of the Lovenox patent's fraudulent underpinnings when Aventis engaged in enforcement conduct against Amphastar."). *See* Req. Ex. 5 at 25.

and filed sham litigation based on bogus patents – all in order to obtain or maintain their drug monopolies. As was the case in *Zenith*, Plaintiffs have alleged Defendants' propensity for manipulating the PTO and FDA processes, and, therefore, Plaintiffs have pleaded sufficient allegations to justify an injunction against Defendants from committing similar acts in the future.[22]

IV. Plaintiffs Have Standing to Assert Their State-Law Claims

A. Plaintiffs Have Alleged Standing

Defendants concede that third-party payors have standing in all states where their members reside. *See In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 156 (E.D. Pa. 2009). Moreover, the Amended Complaint alleges that Pennsylvania Employees Benefit Trust Fund has 270,000 members in various states around the country and that Philadelphia Federation of Teachers Health and Welfare Fund has approximately 20,000 members across several states. Am. Comp. ¶¶ 12 & 14. Nothing more needs to be alleged at the motion to dismiss stage to show standing. *See King Drug Company of Florence v. Cephalon, Inc.*, 702 F.Supp.2d 514, 538 (E.D. Pa. 2010) ("*Provigil*") (holding similar allegations regarding the same plaintiff sufficient to allege standing under all state statutes).

B. Whether a Class Representative Can Raise Claims on Behalf of Other Class Members Is a Class Certification Issue

Even if Plaintiffs had not pleaded standing, the issue of whether the Named Plaintiffs can raise claims on behalf of other class members is a class certification issue. Under Rule 23, a named

[22] Defendants may argue that some of these similar anticompetitive acts have yet to be *proven* because the cases mentioned above have either not yet gone to trial, are on appeal, or were dismissed after confidential settlements. But Plaintiffs are under no duty on a motion to dismiss to *prove* these allegations. While it is true that for an injunction to issue Plaintiffs will *ultimately* have to *prove at trial* that "there exists some cognizable danger of recurrent violation" of the Sherman Act by Defendants, it is also true that at the *pleading stage* it is sufficient to simply *allege* the facts which show the danger of threatened loss or damage.

plaintiff may file a lawsuit and represent another person in that lawsuit if, among other things, "the claims . . . of the representative part[y] are typical of the claims" of the other person. Fed. R. Civ. P. 23(a)(3). Here, the Named Plaintiffs seek to represent other class members because the Named Plaintiffs' claims are typical of the claims of the class. In fact, no one disputes that the Named Plaintiffs here would not have standing to bring a lawsuit on behalf of other class members ***but for*** Rule 23.

Thus, the ability of a named plaintiff to prosecute an action on behalf of a particular class member under a particular state law is an analysis that must be addressed at the class certification stage. Although standing may generally be a threshold inquiry resolved on a motion to dismiss in a routine case, a class action simply calls for a different analysis that must be done at the class certification stage. The Supreme Court made this clear in *Amchem Products, Inc. v. Windsor*, 117 S. Ct. 2231, 2244 (1997), and *Ortiz v. Fibreboard Corp*., 119 S. Ct. 2295, 2307 (1999):

> [When] class certification issues are, as they were in *Amchem*, "logically antecedent" to Article III concerns, and themselves pertain to statutory standing, [they] may properly be treated before Article III standing.

119 S. Ct. at 2307 (internal citations omitted).

Recently, Chief Judge Preska of this Court addressed the "logically antecedent" issue in *In re Digital Music Antitrust Litig.*, No. 06-md-1780, 2011 WL 2848195 (S.D.N.Y. July 18, 2011), where the named plaintiffs brought claims under fourteen states where none of them resided. Judge Preska reviewed the case law and concluded that where "'class certification is the ***source*** of the potential standing problems,' class certification should ***precede*** the standing issue." *Digital Music*, 2011 WL 2848195, at *9 (emphasis added) (citing *In re Grand Theft Auto Video Game Litig*., No. 06-md-1739, 2006 WL 3039993, at *2 (S.D.N.Y. Oct 25, 2006); *Blessing v. Sirius XM Radio, Inc*.,

756 F.Supp.2d 445, 451 (S.D.N.Y. 2010); *In re Buspirone Patent Litig.*, 185 F.Supp.2d 363, 377 (S.D.N.Y. 2002) ("*BuSpar*"). Because the named plaintiffs in *Digital Music* had standing to sue the defendants in their home state, the only issue was whether the named plaintiffs' claims and injuries were sufficiently typical of those of the class to justify the prosecution of a larger class action. *Digital Music,* 2011 WL 2848195, at *10 (because "class certification is logically antecedent to standing in this case, . . . the Court will consider standing after class certification has been resolved.").[23]

The same analysis pertains here. Defendants do not dispute that the Named Plaintiffs have standing under the statutes of their home states; rather, they dispute only whether the Named Plaintiffs will have standing under other state statutes once the issue of class certification is resolved. *See also In re Polyurethane Foam Antitrust Litig.*, No. 10-md-2196, 2011 WL 3204712, at *18-19 (N.D. Ohio September 15, 2011) ("This Court would similarly confuse Article III standing and Federal Civil Rule 23's requirements if it would, at this stage [on a motion to dismiss], dismiss all state-law claims but those of the jurisdictions in which the named Indirect Purchaser Plaintiffs reside, or to which they are connected.").

Defendants cite several cases that decided the issue of class standing on a motion to dismiss instead of waiting until class certification. But most of these opinions do not even mention *Ortiz* or *Amchem*,[24] or they cite *In re Terazosin Hydrochloride Antitrust Litig.* ("*Hytrin*"), 160 F.Supp.2d

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[23] Judge Preska distinguishes cases holding otherwise (some which defendants cite here, such as *In re Flonase*) as cases where "the standing of the *named plaintiffs"* were in question or "the standing of each plaintiff involved nuances in the conduct affecting each plaintiff." *Digital Music*, 2011 WL 2848195, at *9 (noting that such exceptions generally occur in securities cases). Neither situation exists in this case.

[24] *In re Checking Account Overdraft Litig.*, 694 F.Supp.2d 1302 (S.D. Fla. 2010) (failing to analyze *Ortiz* or *Amchem*); *In re: G-Fees Antitrust Litig.*, 584 F.Supp.2d 26 (D.D.C. 2008) (same);

1365 (S.D. Fla. 2001), for support[25] (but *Hytrin* has recently been discredited for failing to analyze *Ortiz* and *Amchem* and instead relying on an outdated Eleventh Circuit opinion),[26] or they simply do not follow the law of the Southern District of New York.[27] Thus, to the extent that the Court finds that standing is an issue, the Court should wait until class certification to resolve it.

IV. Plaintiffs Have Sufficiently Alleged Their State-Law Claims

A. Plaintiffs Have Sufficiently Alleged Their Consumer Protection Claims

Defendants seek dismissal of claims brought by Plaintiffs under several consumer protection statutes, contending that an allegation of deception on a consumer is required under all of the statutes. While that proposition is certainly not true for all consumer protection statutes,[28] it would not matter if it were true for every consumer protection statute. Plaintiffs have in fact alleged deception by Defendants that led to consumers paying too much for DDAVP. Specifically, Plaintiffs allege that Defendants repeatedly lied to and deceived the PTO in order to keep their monopoly on DDAVP. Am. Comp. ¶¶ 56-76. The Federal Circuit has held that this conduct supports the conclusion that Defendants "deliberately concealed" from the PTO the fact that the declarants were

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[25] *See, e.g., In re Packaged Ice Antitrust Litig.*, 779 F.Supp.2d 642 (E.D. Mich. 2011) (citing *Hytrin*) (Moreover, *Packaged Ice* and its reasoning was not followed by the court in *Polyurethane Foam* because *Packaged Ice* ignored controlling Sixth Circuit precedent relating to the issue of "logically antecedent"); *In re Flonase Antitrust Litig.*, 692 F.Supp.2d 524, 533 (E.D. Pa. 2010) (citing *Hytrin); In re Ditropan XL Antitrust Litig.*, 529 F.Supp.2d 1098, 1107 (N.D. Cal. 2007) (citing *Hytrin* and following *Easter v. American West Financial*, 381 F.3d 948 (9th Cir. 2004); *In re Graphics Processing Units Antitrust Litig.*, 527 F.Supp.2d 1011 (N.D. Cal. 2007) (same). *Cf. Jepson v. Ticor Title Ins. Co.*, No. 06-1723, 2007 WL 2060856, at *2 (W.D. Wash. 2007) (distinguishing *Easter* as a case that applies only to situations where a plaintiff cannot trace their injuries to a particular *defendant*).

[26] *Woodard v. Fidelity Nat'l Title Ins.*, No. 06-1170, 2007 WL 5173415, at *4 (D.N.M. Dec. 4, 2007) ("This Court cannot lightly disregard controlling Supreme Court precedent and chooses not to do so today.").

[27] *Wellbutrin XL,* 260 F.R.D. at 155 (distinguishing *BuSpar* – a Southern District of New York opinion) ("Again, the Court declines to follow the *Buspirone* decision."). *Wellbutrin XL* also cites the 11th Circuit opinion that preceded *Ortiz* and *Amchem* by more than 10 years that *Hytrin* improperly relied on for its holding. *See id.* at 152.

[28] *See, e.g.,* discussion *infra* regarding New Mexico and Idaho.

Defendants' own paid consultants. *Ferring B.V.*, 437 F.3d at 1193 (affirming summary judgment). Defendants then filed sham litigation against the generic manufactures to stop generic DDVAP from coming to market, enabling the Defendants to continue charging consumers monopoly prices for DDAVP. Am. Comp. ¶¶ 83-101.

Defendants lied to and deceived yet another government agency by filing a frivolous citizen petition with the FDA. Specifically, Defendants requested studies suggesting that a competitor's generic product may not be safe for children. Am. Comp. ¶¶ 104-05, 109. Worth noting is the fact that Defendants' citizen petition was a public document that any class member interested in purchasing generic DDAVP could review. The FDA denied the citizen petition as baseless. Am. Comp. ¶ 115-16. More importantly, one of the reasons it was denied was because Ferring, despite 21 C.F.R. § 10.30's clear mandate, somehow "forgot" to advise the FDA of a prior Aventis Study directly contradicting its argument regarding the safety and efficacy of generic DDAVP for children. In other words, Ferring's filing of the Citizen Petition amounted to "*deceptive* conduct." Am. Comp. ¶ 116. *Cf. In re Flonase*, 2011 WL 4464823, at *12 (E.D. Pa. Sept. 26, 2011) (allegations that defendants knew that their citizen petition to the FDA contained information contradicted by information excluded from its petition may be sufficient to state a consumer protection claim).

Defendants contend that the deception they perpetrated on the PTO and the FDA is insufficient to prove deception on consumers. Many courts, however, have held a direct representation to a consumer is unnecessary. *See, e.g., Abbott Lab. v. Teva Pharm.*, ("*Tricor*") 432 F.Supp.2d 408, 433-34 (D. Del. 2006) (holding that while there may be no direct consumer deception, consumer protection claims would not be dismissed because "the patents were obtained through fraud"); *Provigil*, 702 F.Supp.2d at 539 (entering into confidential illegal agreements with

the goal of keeping the price of Provigil artificially high, even without direct deceptive conduct on consumers, sufficient to state a claim under various consumer protection statutes); *In re Intel Corp. Microprocessor Antitrust Litig.*, 496 F.Supp.2d 404, 417-18 (D. Del. 2007) (deceptive acts, even if they are not directed toward the plaintiffs, are sufficient to state a claim under seven consumer protection statutes so long as the acts "ultimately impacted" the plaintiffs).

Because Plaintiffs have adequately alleged their consumer protection claims, Defendants' motion to dismiss Plaintiffs' consumer protection claims should be denied. The cases that Defendants cite regarding the states of (1) Arizona, Colorado, Idaho Michigan and Nevada;[29] (2) New Mexico;[30] (3) New York;[31] and (4) South Dakota and Tennessee,[32] do not suggest otherwise.

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[29] *Compare Sheet Metal Workers v. Glaxosmithkline, PLC*, 737 F.Supp.2d 380, 404 n.10 (E.D. Pa. 2010) ("*Sheet Metal*") (cited by defendants, which found no deception because plaintiffs could not properly allege a *Walker Process* claim, and where no citizen petition fraud claim was even alleged) *with In re Flonase*, No 08-3301, 2011 WL 4464823, at *12 (E.D. Pa. Sept. 26, 2011) (allegations that defendants knew that its citizen petition contained information contradicted by information excluded from its petition may be sufficient to state a claim under Arizona's consumer protection statute) *and In re New Motor Vehicles Canadian Export Antitrust Litig.*, 350 F.Supp.2d 160, 184-85 (D. Me. 2004) ("*New Motor Vehicles*") (holding that Idaho Consumer Protection Act ("ICPA") covered antitrust conduct and unconscionable acts; ICPA satisfied where it was alleged that defendants attempted to unlawfully maintain a gross price disparity in new cars) *and Wilcom Pty. Ltd. v. Endless Visions*, 128 F.Supp.2d 1027, 1033 (E.D. Mich. 1998) (Michigan Consumer Protection Act governs unfair competition); *Compare* Nev. Rev. Stat § 598.0915(9) (prohibiting bait and switch) *with* Nev. Rev. Stat. § 598.0953(1) ("[e]vidence that a person has engaged in a deceptive trade practice is prima facie evidence of intent to injure competitors and to destroy or substantially lessen competition.").

[30] *Compare Stevenson v. Louis Dreyfus Corp.*, 811 P.2d 1308, 1311 (N.M. 1991) (misrepresentation made in connection with a sale is required) *with Digital Music*, 2011 WL 2848195, at *13 ("allegation that plaintiffs paid supracompetitive prices for the music they purchased 'is sufficient to allege gross disparity,'" which is sufficient to state a claim under New Mexico Unfair Practices Act), *and In re TFT-LCD (Flat Panel) Antitrust Litig.*, No. 07-1827, 2011 WL 4501223, at *2 (N.D. Cal. Sept. 28, 2011) (same), *and In re Aftermarket Filters Antitrust Litig.*, No. 08-4883, 2009 WL 3754041, at *9 (N.D. Ill. Nov. 5, 2009) (same), *and In re Chocolate Conf. Antitrust Litig.*, 602 F.Supp.2d, 538, 585-86 (M.D. Pa. 2009) (same, noting that "the court adopts the reasoning of the latter cases, which evince a compelling trend favorable to consumer protection claims in price-fixing actions.").

[31] *Compare Sheet Metal*, 737 F.Supp.2d at 404 n.10 (cited by defendants, which found no deception because plaintiffs could not properly allege a *Walker Process* claim, and where no citizen petition fraud claim was even alleged), *and Wellbutrin XL*, 260 F.R.D. at 164-65 (holding that deception on government agencies is too remote to state a claim under New York law), *with Provigil*, 702 F.Supp.2d at 539 (citing *Cox v. Microsoft Corp*. 778 N.Y.S.2d 147 (N.Y. App Div. 2004), *and Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 258, 264 (2d Cir. 1995) (false and deceptive statements to the New York City Bureau of Standards and Appeals sufficient to state a claim under New York law), *and TFT-LCD*, 2011 WL 4501223, at *3 (to state a claim under section 349, a plaintiff need only allege that defendants concealed its anticompetitive activities; "plaintiffs need not have been aware of defendants' deceptive conduct to recover

B. Plaintiffs Have Properly Alleged Intrastate Effects

Defendants next argue that Plaintiffs' claims under the state statutes of North Carolina, New Hampshire and Mississippi should be dismissed because Plaintiffs have not sufficiently alleged that Defendants' conspiratorial conduct affected these particular states. Jt Mtn at 21-22. Chief Judge Preska recently addressed the "intrastate conduct" issue in *Digital Music*, holding that an allegation that "Defendants' conduct was in a continuous and uninterrupted flow of intrastate and interstate commerce throughout the United States" was sufficient for the seven state statutes at issue, including North Carolina. *Digital Music*, 2011 WL 2848195, at *10-11. In fact, Judge Preska noted that an "allegation of conduct throughout the United States and in each listed state would be an example of 'superior pleading.'" *Id.* at *11 n.9. Here, Plaintiffs allege that "Defendants' conduct caused pharmacies ***in every state*** to charge higher prices for DDAVP . . . including transactions that occurred ***purely intrastate***." Am. Comp.¶ 142.[33]

There is nothing in Judge Preska's analysis (which addressed the intrastate conduct issue generally with regard to seven states including North Carolina) that would suggest that the outcome would be any different had Mississippi or New Hampshire been at issue. *See, e.g., Provigil*, 702

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under section 349."), *and Flonase*, 2011 WL 4464823, at *12 (allegations that Defendants knew that its citizen petition to the FDA contained information contradicted by information excluded from its petition sufficient to state consumer protection claim); *New York v. Feldman*, 210 F.Supp.2d 294, 302 (S.D.N.Y. 2002) (antitrust violations constitute the kind of deceptive acts and practices contemplated by consumer protection statutes).

[32] *Compare* S.D.C.L. § 37-24-6(1) (deceptive acts must be made "in connection with the sale" of a product) *with Brookings Mun. Utils. v. Amoco Chem. Co.*, 103 F. Supp. 2d 1169, 1177-80 (D.S.D. 2000) (defendants "cannot escape liability to plaintiffs for their alleged misrepresentations simply because they did not make any statements directly to plaintiffs."), *and Tricor*, 432 F.Supp.2d 408, 433-34 (D. Del. 2006) (holding that while there may be no direct consumer deception, consumer protection claims would not be dismissed), *and New Motor Vehicles*, 350 F.Supp.2d at 196-97, 202-03 (holding that South Dakota's consumer protection statute is applicable if a plaintiff alleges fraud).

[33] *See also Sheet Metal*, 737 F.Supp.2d at 400 (allegations that a drug was sold and promoted in North Carolina per an unlawful monopoly sufficient to show intrastate effects).

F.Supp.2d at 539 ("Plaintiffs need 'only have to plead facts that would lead to a reasonable inference that the defendant . . . wanted the Mississippi vendors to charge Mississippi consumers a higher price as a result of the lack of competition.") (citing *Hood v. BASF Corp*., 2006 WL 308378, at *10 (Miss. Ch. Jan. 17, 2006); *In re: TFT-LCD (Flat Panel) Antitrust Litig.,* 599 F.Supp.2d 1179, 1188 (N.D. Cal. 2009) (allegation that plaintiffs paid supracompetitive prices in Mississippi sufficient); *In re: Chocolate Conf. Antitrust Litig*., 749 F.Supp.2d 224, 234-35 (M.D. Pa. 2010) (New Hampshire statute is satisfied as long as plaintiffs allege that price-fixed products "were introduced into the New Hampshire market.").

C. It Is Premature to Determine Whether the Tennessee Consumer Protection Act Permits Class Certification

Defendants next argue that the Court should dismiss Plaintiffs' claims under the Tennessee Consumer Protection Act ("TCPA") because it does not permit class actions. Whether or not the TCPA permits a class action,[34] raising such an argument on a motion to dismiss is premature since Plaintiffs have not yet moved for class certification on any of their claims. *See In re K-Dur Antitrust Litig.*, 338 F.Supp.2d 517, 541-43 (D.N.J. 2004) (deferring decision on whether alleged state-specific restrictions are relevant until after class certification).

D. Plaintiffs State a Claim for Unjust Enrichment

In Count III, Plaintiffs assert claims for restitution, disgorgement and imposition of a constructive trust for unjust enrichment under the laws of the 50 states and the District of Columbia.

[34] *Compare Ham v. Swift Transportation Co, Inc*., No. 2:09-2145, 2011 WL 2712745 (W.D. Tenn. July 1, 2011) (certifying class under TCPA) *with Walker v. Sunrise Pontiac-GMC Truck, Inc*., 249 S.W.3d 301 (Tenn . 2008) (TCPA does not provide for class certification).

1. *Illinois Brick* Does Not Apply to Unjust Enrichment Claims

In moving to dismiss Count III, Defendants rely on *Hytrin*, *Sheet Metal*, and *New Motor Vehicles* to argue that Plaintiffs cannot seek unjust enrichment in states that, based on *Illinois Brick Co. v. Illinois*, 97 S. Ct. 2061 (1977), do not permit indirect purchaser actions under their antitrust statutes. Defendants claim it would be an "end-run" around statutory limitations on remedies. In response to the "end-run" argument, however, the court in *Provigil*, 702 F.Supp.2d at 539-40, held that "[s]everal courts . . . have found just the opposite. . . .[and that] unjust enrichment claims are viable regardless of the applicable state antitrust laws. *Id.*[35]

2. Plaintiffs Do Not Have to Allege a Direct Benefit

For the states of Florida, Idaho, New York and North Dakota, Defendants argue that plaintiffs must allege that plaintiffs gave a direct benefit to the defendant. In *Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 668-71 (E.D. Mich. 2000), the court rejected the identical argument, sustaining unjust enrichment claims under the laws of several states, including New York. *See also Provigil,* 702 F.Supp.2d at 540 n.16 (adopting *Cardizem's* analysis regarding privity for New York unjust enrichment claim); *MacMorris v. Wyeth, Inc.*, No. 04-596, 2005 WL 1528626, at *4 (M.D. Fla. June 27, 2005) (holding that privity is not an element of a Florida unjust enrichment claim); *Sheet Metal*,737 F.Supp.2d at 428-29 (rejecting the argument that unjust enrichment claims in general require conferral of a direct benefit and requiring "clear authority" to rule otherwise).

Here, plaintiffs have alleged they conferred a benefit on Defendants by purchasing DDAVP

[35] If Defendants were correct, then states would apply *Illinois Brick* across the board for all state-law claims, whether derived from statute or common law. Yet several states that follow *Illinois Brick* to prevent indirect actions under their antitrust statutes, do not follow *Illinois Brick* to prevent indirect purchaser claims under their consumer protection laws. *See, e.g.*, *Ciardi v. F. Hoffman-La Roche, Ltd.*, 762 N.E.2d 303 (Mass. 2002); *Mack v. Bristol-Myers Squibb Co.*, 673 So.2d 100 (Fla. 1st DCA 1996). It is simply incontrovertible that *Illinois Brick* does not act as a universal preemption rule regarding other state-law claims even if these claims are based on unfair business practices.

at inflated prices. These allegations are sufficient to show that a benefit was bestowed on Defendants, and that the Defendants were therefore unjustly enriched at Plaintiffs' expense. *See, e.g., K-Dur*, 338 F.Supp.2d at 543-46 (rejecting argument to dismiss unjust enrichment claims on a motion to dismiss because "critical inquiry" is whether the defendant's benefits are related to the challenged conduct); *Sheet Metal,* 737 F.Supp.2d at 428 ("Many courts in addition to this one have ruled that a direct relationship between an antitrust plaintiff and defendant is not necessary to assert an unjust enrichment claim."); *In re Terazosin Hydrochloride,* 220 F.R.D. 672, 698 (S.D. Fla. 2004) (unjust enrichment claims certified where defendants' unlawful profits were directly attributable to consumer purchases).

3. Unjust Enrichment Claims are Independent Claims

Defendants argue that if Plaintiffs' state antitrust or consumer protection claims fail, then their unjust enrichment claims must fail too since they are based on the same anticompetitive conduct. In *Cardizem*, however, the court held that indirect purchasers could bring a claim for unjust enrichment regardless of whether they could pursue state antitrust claims. *Cardizem*, 105 F.Supp.2d at 669-71. In any event, as we have shown above, Plaintiffs' statutory state-law claims are sufficiently pleaded and should not be dismissed.

CONCLUSION

None of Defendants' arguments require dismissal of Plaintiffs' claims. Plaintiffs therefore respectfully request that the Court deny Defendants' Joint Motion to Dismiss.[36]

[36] In the event that this Court finds that Plaintiffs have not properly alleged one of their claims, Plaintiffs respectfully request that the Court permit Plaintiffs to file an amended complaint.

Dated: October 21, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Kevin B. Love, hereby certify that, pursuant to Court Order, on October 21, 2011, I electronically served the foregoing document on counsel for Defendants.

s/ Kevin B. Love
Kevin B. Love

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